UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------X

[UNDER SEAL],

Relator,

v.

[UNDER SEAL],

Defendants.

----------X

Civil Action: 16-CV-1090

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730 (b)(2)

SECOND AMENDED COMPLAINT FOR VIOLATIONS OF FEDERAL FALSE CLAIMS ACT

JURY TRIAL DEMANDED

FILED
IN CLERK'S OFFICE
US DISTRICT COURT E.D.N.Y.
★ FEB 09 2022 ★
BROOKLYN OFFICE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel*, YNKDY-2, STATE OF NEW YORK, ex rel, YNKDY-2, STATE OF NEW JERSEY, *ex rel* YNKDY-2, Relator, v. Shiel Medical Laboratory; Shiel Holdings, LLC Fresenius Medical Care; BIM Medical, Inc.; Jack Basch; Does 1-10, Inclusive, et al., Defendants.	Civil Action: 16-CV-1090 FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730 (b)(2) SECOND AMENDED COMPLAINT FOR VIOLATIONS OF FEDERAL FALSE CLAIMS ACT JURY TRIAL DEMANDED

1. Relator brings this action against defendants pursuant to the False Claims Act 31 U.S.C. §3729 et. seq. ("FCA") seeking treble damages and civil penalties.

2. Shiel Medical Laboratory was founded in 1962 and was purchased by Jack Basch, Michael Inzlicht, and Arthur Meisels in 1994. It's gross receivables and net revenue grew rapidly, to the point where the laboratory business was purchased by Fresenius Medical Care of North America (hereafter, "Fresenius") in 2013 for nearly quarter of a billion dollars. In November of 2013 Shiel became BIM Medical, Inc. Its President Chief Executive Officer is Jack Basch.

3. Shiel performs laboratory testing which, when used appropriately, informs physicians and other health care providers of chemical and biochemical changes in a patient's body. When properly used this information can be useful to the diagnosis and treatment of disease.

4. Since at least 1996, Shiel has knowingly submitted hundreds of millions of dollars in false claims to the Medicare and New York and New Jersey Medicaid programs for tests that were not reasonable and necessary or that were furnished pursuant to prohibited referrals that resulted from Shiel's improper financial relationships with physicians and with skilled nursing facilities, in violation of the physician self-referral prohibition, 42 U.S.C. § 1395nn (commonly known as the "Stark Law"), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

5. As Defendants knew, Medicare only covers tests that are reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury, based on his or her medical condition. 42 U.S.C. § 1395y(a)(1)(A). The need for each test for each patient must be individually assessed and documented in the patient's medical chart. 42 C.F.R. §§ 410.32(a), (d)(2). Defendants nonetheless sought to, and did, cause many physicians to routinely order extensive and expensive laboratory tests merely to make more money.

6. Shiel also paid illegal kickbacks to physicians and nursing homes in the free advertising, computer and hardware purchases to facilitate the shift to electronic medical records, gifts, parties, and expensive meals. In addition, Shiel offered kickbacks in the form of substantial discounts to nursing homes on their Medicare Part A lab tests in exchange for an exclusive contract to Shiel to do all the lab work for the nursing homes' Medicare Part B patients. Relator's principal was responsible for negotiating these discounts and therefore had personal knowledge of these kickbacks for the last twenty years.

I. JURISDICTION, VENUE, PARTIES

7. This action arises under the FCA, as amended, 31 U.S.C. §§ 3729-33, and under common law theories of payment by mistake of fact and unjust enrichment. This Court has jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1345 and 1367(a).

8. Venue is proper in this Eastern District of New York pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

9. This Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) and because Defendant resides and transacts business in this District.

10. Relator is a California corporation whose principal held a senior position within Shiel and who has direct and personal knowledge of the matters alleged herein. Before this suit was filed, Relator's principal and agent (Relator's Principal / Agent and Relator are collectively and individually referred to as "Relator") voluntarily and on his own initiative contacted federal law enforcement and submitted evidence of defendants' wrongdoing.

11. Defendant Shiel Medical Laboratory was a private corporation incorporated in the State of New York in with its principal place of business in Brooklyn, New York.

12. Defendant BIM Medical, Inc., is another private corporation incorporated in the State of New York with its principal place of business in Brooklyn, New York. It was owned by Jack Basch, Michael Inzlicht, and Arthur Meisels, the same partners who owned and sold Shiel Medical Laboratories.

13. Defendant Fresenius Medical Care is a publicly traded corporation incorporated in Germany with its principal place of business in Bad Homburg, Germany. Its principal headquarters in the United States is in Waltham, Massachusetts, from which it conducts a nationwide health care business which last year generated $15.8 billion in revenue.

14. Defendant Shiel Holdings, LLC is a private corporation incorporated in the State of Delaware with its principal place of business in Waltham, Massachusetts.

15. Defendant Jack Basch is an individual residing within the Eastern District of New York.

16. Each and every one of the fictitiously named Doe Defendants is an individual or corporation which has submitted or caused the submission of false claims, acting in concert with one or more of the other defendants.

17. Relator is informed and believes and based thereon alleges that each and every one of the defendants has acted as the agent, director, or co-venturer of every other defendant to submit or cause the submission of false claims to the United States and to the States of New York and New Jersey.

II. LAW

A. The Federal False Claims Act

18. The FCA provides, in pertinent part, that a person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains . . . .

31 U.S.C. § 3729(a)(1).[1]

19. For purposes of the FCA,

> (1) the terms "knowing" and "knowingly"—
>
> (A) mean that a person, with respect to information—
>
> (i) has actual knowledge of the information;
>
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to

defraud[.] 31 U.S.C. § 3729(b)(1).

20. An overpayment is a payment by a federal entity to a provider or supplier in excess of what was due and payable. An overpayment may include payment for non-covered

[1]The FCA was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009. Sections 3729(a)(1) of the prior statute applies to conduct that occurred before FERA was enacted, and Section 3729(a)(1)(A) of the revised statute applies to conduct after FERA was enacted. Section 3729(a)(1)(B) is applicable to all claims in this case by virtue of Section 4(f) of FERA.

items or services including services that are not reasonable and necessary in accordance with the Medicare rules. An overpayment may be received through an innocent billing error or through a mistake of the contractor. 42 U.S.C. Section 1320a -7k(d)(1) warns that "returning the overpayment . . . is an obligation (as defined in 3729(b)(3) of title 31 for purposes of section 3729 of such title."

21. As of May 24, 2010, the effective day of the legislation that established subsection 7k(d)(1), each day that a provider retains an overpayment, it is violating the Federal False Claims Act.

22. A refusal to calculate or estimate the amount of overpayment refunds owed is a separate violation of 31 U.S.C. §3729(b)(3) of the False Claims Act.

B. The Medicare and Medicaid Programs

1. The Medicare Program

23. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*., known as the Medicare program. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1. CMS administers the Medicare program. At all times relevant to this complaint, CMS contracted with private contractors, referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. The Medicare program consists of four parts: A, B, C, and D. Defendants billed Medicare under Part B, which covers certain medical services, such as clinical laboratory test services, furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k(a)(2)(B).

24. To continue to participate in the Medicare program as an enrollee, clinical laboratories, such as Shiel were required to submit a Medicare Enrollment Application.

25. Laboratories also complete Form CMS-855B to change information or to reactivate, revalidate and/or terminate Medicare enrollment.

26. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

27. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to all of the laws, regulations, and program instructions of the Medicare program."

28. Relator is informed and believes and based thereon alleges that authorized officials for Shiel Medical Laboratory and later Fresenius signed the certification statement in Section 15 of Form CMS-855B, indicating that they understood that the laboratory was required to comply with Medicare laws, regulations, and program instructions, which include, but are not limited to, the Stark Law and the Anti-Kickback Statute.

29. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

30. To obtain Medicare and Medicaid reimbursement for certain outpatient items or and services, providers and suppliers submit a claim form known as the CMS 1500 form ("CMS1500") or its electronic equivalent known as the 837P form. The information the provider or supplier includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common

Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source."

31. Beginning in 1996, laboratories submitting bills to Medicare were required to ensure that the ordering physician had identified the specific medical condition which justified the laboratory test or tests. The medical condition was to be described using the International Classification of Diseases, Edition 9 (ICD-9), which coded different disease states[2]. The ICD-9 code used to justify the laboratory test must be kept on file by the clinical laboratory.

32. Medicare Part A authorizes the payment of federal funds for hospitalization and post-hospitalization care. 42 U.S.C.§ 1395c-1395i-2(1992). Medicare Part B authorizes the payment of federal funds for medical and other health services, including without limitation physician services, supplies and services incident to physician services, labor tory services, outpatient therapy, diagnostic services, and radiology services. 42 U.S.C. § 1395(k),(i), (s).

33. For enrollees of Medicare and other federal insurance programs, Part A of the program provides coverage for up to 100 days for skilled therapy services provided to a beneficiary while inpatient in a SNF. For Medicare Part A patients, Medicare reimburses the SNF on a prospective payment system (PPS) with the prospective payments adjusted to take into consideration the patient's acuity and likely care needs. Payment for lab services under Part A are included in the SNF PPS rate.

[2]Beginning October1, 2015, CMS required that the new, ICD-10 codes be used instead.

34. Part B of the Program provides coverage for skilled therapy to beneficiaries who have either exhausted their Part A benefit or are not otherwise entitled to Part A coverage. Lab services for Medicare patients covered under Part B are either billed directly by the laboratory providing the services or, if the SNF provides the services itself (and is properly qualified under the Clinical Laboratory Improvement Act) the SNF may directly bill Medicare for the services. In addition to the Medicare fee schedules for the tests, the laboratories may also bill for obtaining the specimen and for travel to the SNF patient.

35. Because a SNF which receives PPS reimbursement for Part A patients is being paid for the anticipated cost of lab services, the SNF is then financially liable for lab services those patients require.

36. Medicare requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and unique physician identification number for the referring physician. 42 U.S.C. § 1395l(q)(1).

37. From 2007 to the present, National Government Services (NGS) has been responsible for processing Medicare Part B claims in New York. As Defendants performed all of its tests at facilities in New York, it submitted all claims to NGS.

III. LOCAL COVERAGE DETERMINATIONS (LCDs)

38. The U.S. Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) promulgate federal regulations and National Coverage Determinations (NCDs) upon which Medicare Fiscal Intermediaries/carriers rely to make coverage determinations for claims for medical services and items provided to beneficiaries. HHS adopts NCDs to exclude certain items and services from coverage on a national level that are not reasonable and necessary under HHS's interpretation of the

Medicare Act. Federal regulations and NCDs are binding on all MACs nationwide. (42 U.S.C. 1395ff(f)(1)(B).

39. In the absence of a NCD, Fiscal Intermediaries/Carriers, now Medicare Administrative Contractors (MACs) and their divisions such as the DMERCs, were authorized to establish policies now known as (LMRPs) Local Coverage Determinations (LCDs).

40. When a service is not governed by a NCD, each Carrier could issue an LCD identifying indications and limitations of coverage and payment. *See* 42 U.S.C. 1395kk-1(a)(4).

41. LCDs establish specific criteria for initial and continued coverage of a service and identify circumstances under which Medicare will deny coverage for a service as not reasonable and necessary. *See* 42 C.F.R. §400.202..The Social Security Act defines Local Coverage Determination as:

> (B) Definition of local coverage determination.
> For purposes of this section, the term "local coverage determination" means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A). 42 U.S.C.
> §1395ff (f)(2)(B).

42. Each of MACs publishes and provides LCDs to the providers in its region.

43. Medicare does not pay for medical treatments or diagnostic services that are not reasonable and necessary. 42 U.S.C. §1395y(a)(1)(A), 42 CFR §411.15(k).

44. CMS publishes a Medicare Program Integrity Manual which instructs the MACs that when determining whether a treatment is reasonable and necessary under section 1395(y)(a)(1)(A), they may apply the so-called "reasonably feasible and medically appropriate

least costly" alternative policy. (Chapter 13.4.A, Rev. 71, April 9, 2004). Chapter 13 of the Medicare Program Integrity Manual provides the following detailed information regarding LCDs:

> 13.1.3 - Local Coverage Determinations (LCDs)
> (Rev. 165, Issued: 10-06-06, Effective: 09-11-06, Implementation: 10-26-06)
>
> Section 522 of the Benefits Improvement and Protection Act (BIPA) created the term "local coverage determination" (LCD). An LCD is a decision by a Medicare administrative contractor (MAC), fiscal intermediary or carrier whether to cover a particular service on a MAC-wide, intermediary wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the service is reasonable and necessary).
> . . .

2. <u>The New York Medicaid Program</u>

45. The New York State Medicaid Program is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq*. Medicaid is a joint federal-state program that provides healthcare benefits, including laboratory services coverage, for certain groups including the poor and disabled. The New York Medicaid program is required to implement a "State Plan" containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage, is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d (b).

> Medicaid guidance, (e.g., the "New York Medicaid Provider Manual for Laboratory Services) is issued to give Medicaid providers the policies and procedures needed to properly bill and be appropriately paid for covered services provided to eligible New York Medicaid recipients. Physicians and laboratories certify in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid.

> New York's "Medicaid Provider Enrollment Application" must be completed by any person or entity desiring to receive payment for services provided to Medicaid recipients. To be eligible to receive direct or indirect payments for services rendered to New York Medicaid Program recipients, a provider must certify that the provider understands "that false claims, statements, documents, or concealment of material facts may be prosecuted under applicable federal and state laws."

New York Provider Enrollment Application, Section VII, Certification,

46. The New York Medicaid Provider Laboratory Handbook warns that Medicaid does not pay for services unless they are medically necessary as evident from documentation in the enrollee's medical record. The Handbook also makes clear the warning that knowingly making a claim for inappropriate or unnecessary services is forbidden. Finally, with each claim,Shiel and Fresenius are required to certify that the laboratory services were furnished in accordance with applicable federal and state laws and regulations, and that no material fact has been omitted from the claim form.

47. Pursuant to New York's Electronic Claims Submission Agreement, all providers must abide by all Federal and State statutes, rules, regulations, and manuals governing the New York Medicaid program. The agreement also requires providers to certify that each claim is in compliance with all federal and state laws and the conditions on the claim form, including that "the services . . . were medically indicated and necessary to the health of this patient" and that the provider understands "that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

48. In addition, New York Codes, Rules and Regulations Title 18, Section 505.7 g(1) specifically requires that NY Medicaid (the NYS Medical Assistance program) "payment for

laboratory services will be in an amount equal to the lower of: the amount specified in the MA fee schedule for laboratory services or the fee charged for laboratory services provided to the general public by the laboratory."18 CRR-NY 505.7 g (1). Therefore any discounts that result in payment lower than the MA fee schedule are not permitted.

49. Shiel offered nursing homes substantial discounts on their Medicare Part A lab tests, in exchange for an exclusive contract to Shiel for all Part B work.

50. The discounts offered were intended to induce and actually did induce the nursing homes to give Shiel exclusive contracts for all laboratory services to the homes' Part B patients.

51. The resultant discounts led to Medicare payments which were below the NYS MA fee schedule amount. New York Medicaid, instead of paying the fee schedule rate for these tests, should have been paid the lesser amount (the discounted Medicare rate.)

3. The New Jersey Medicaid Program

52. The New Jersey State Medicaid Program is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq*. Medicaid is a joint federal-state program that provides healthcare benefits, including laboratory services coverage, for certain groups including the poor and disabled. The New Jersey Medicaid program is required to implement a "State Plan" containing certain specified minimum criteria for coverage and payment of claimsin order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federalportion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage, is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d (b).

53. Physicians and laboratories certify in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid. New Jersey's "Medicaid Provider Enrollment Application" must be completed by any person or entity desiring to receive payment for services provided to Medicaid recipients.

4. Regulations Regarding Coverage for Laboratory Tests

54. Medicare and New York and New Jersey Medicaid regulations both make clear that laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury, that laboratory test orders that are not individualized too patient need (or for which the need is not documented in the patient chart) are not covered services, and that claims for such services must be denied.

a. Medicare Coverage for Laboratory Tests

55. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), as set forth at 42 C.F.R. Part 493.

56. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. 42 C.F.R. § 410.32(d)(v). "Clinical laboratory services involve the . . . examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition." Medicare Benefit Policy Manual ("MBPM"), (Pub. 100-02), Ch. 15, § 80.1, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf (visited March 15, 2014).

57. Medicare Part B only covers services, including diagnostic laboratory services, that are reasonable and necessary for the diagnosis or treatment of an illness. *See* 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part

B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning ofa malformed body member[.]")

58. Pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." The MPBM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary [T]he physician must clearly document, in the medical record his or her intent that the test be performed." MPBM, Ch. 15, Section 80.6.1.

59. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. § 410.32(a). Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. §410.32(a). MPBM, Ch. 15, § 80.1.

60. To assess whether those services are reasonable and necessary and whether reimbursement is appropriate, Medicare requires proper and complete documentation of the services rendered to beneficiaries and prohibits payment "to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period. 42 U.S.C. § 1395l(e);

see also 42 U.S.C. § 1395u(c)(2)(B)(i) ("The term 'clean claim' means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) ").

61. Medicare regulations expressly state that a laboratory's claim for a service will be denied if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3)

62. CMS regulations further empower laboratories to request documentation from physicians regarding medical necessity:

> (iii) Medical necessity. The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

63. The Department of Health and Human Services, Office of Inspector General ("HHS-OIG") has published Compliance Program Guidance for Clinical Laboratories in the Federal Register. 63 Fed Reg. 45076 (Aug. 24, 1998), available at https://oig.hhs.gov/authorities/docs/cpglab.pdf. (Visited January 17, 2016.) Among other things, the HHS-OIG guidance clarifies that laboratory order forms should emphasize the need for a justification and assessment of each test ordered and that Medicare does not pay for tests for screening purposes:

64. Therefore, Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record, does not support that the tests were reasonable and necessary for a given patient.

. . .

> a. Requisition design: While HCFA [(CMS)] does not design or approve requisition forms, laboratories should construct the requisition form to capture the correct program information as required by Federal or private health care programs and to promote
> the conscious ordering of tests by physicians or other authorized individuals. The laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill. . . **The form should contain a statement indicating that Medicare generally does not cover routine screening tests.**

. . . .

b. New York Medicaid Coverage for Laboratory Tests

65. New York Medicaid also requires that testing be individualized to the medical needs of patients and must be medically necessary.

c. Self-Referral and Anti-Kickback Prohibitions

(1). The Stark Law

66. The federal physician self-referral prohibition, 42 U.S.C. § 1395nn (commonly known as the "Stark Law") prohibits an entity from submitting claims to Medicare for twelve categories of "designated health services" ("DHS"), including clinical laboratory services, if such services were referred to the entity by a physician with whom the entity had a financial relationship that did not fall within a statutory or regulatory exception. 42 U.S.C. §§ 1395nn; *see also* 42 C.F.R. §§ 411.351 *et seq*.

67. Compliance with the Stark Law is a condition of payment by the Medicare program. Medicare may not pay for any DHS provided in violation of the Stark Law. *See* 42 U.S.C. §§ 1395nn(a)(1), (g)(1).

68. The regulations interpreting the Stark Law require that "[a]n entity that collects

payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis" 42 C.F.R. § 411.353(d).

69. A "financial relationship" includes a "compensation arrangement," which means any arrangement involving any "remuneration" paid to a referring physician "directly or indirectly, overtly or covertly, in cash or in kind" by the entity furnishing the DHS. *See* 42 U.S.C.

§§ 1395nn(h)(1)(A) and (h)(1)(B).

70. Effective October 1, 2008, "a physician is deemed to 'stand in the shoes' of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if -- (A) The only intervening entity between the physician and the entity furnishing [DHS] is his or her physician organization; and (B) The physician has an ownership or investment interest in the physician organization." 42 C.F.R. § 411.354(c)(1)(ii).

71. Under the Stark Law, an "entity is considered to be furnishing DHS if it . . . [is the] entity that has presented a claim to Medicare for the [DHS] .." 42 C.F.R. § 411.351.

72. A "referral" includes "the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any [DHS] for which payment may be made under Medicare Part B " 42 C.F.R. § 411.351.

73. The Stark Law and its interpretive regulations contain exceptions for certain compensation arrangements. The statute and regulations also exempt certain items from the definition of "remuneration," including items "used solely to (I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or (II) order or communicate the result of tests or procedures for such entity." 42 U.S.C. § 1395nn(h)(1)(C)(ii); 42 C.F.R. § 411.351.

(2). The Anti-Kickback Statute

74. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or potentially harmful to patients. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a per se prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. The statute was first enacted in 1972, and was strengthened in 1977 and 1987, to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and ©; 42 U.S.C. § 1320a-7b, Medicare- Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

75. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment, in cash or in kind, to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicare and Medicaid programs. In pertinent part, the statute provides:

> (b) Illegal remunerations . . .
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person–
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

76. Compliance with the Anti-Kickback Statute is a condition of payment by the Medicare program. 42 U.S.C. § 1320a-7(b)(7).

IV. DEFENDANTS' FRAUDULENT SCHEMES

77. Defendants knowingly submitted and caused to be submitted false claims to Medicare and New York and New Jersey Medicaid for non-covered laboratory testing and testing that was not reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 410.32(a); MBPM, Ch. 15, Section 80.6.1.

78. Defendants illegally paid skilled nursing facilities and physicians remuneration in the form of gifts, expensive entertainment, payment of expenses for advertising, payment of expenses for EMR licensing, phlebotomists, and office support staff.

79. Defendants also paid kickbacks to skilled nursing facilities by giving them substantial discounts of Medicare Part A lab work in exchange for exclusive agreements to send Shiel all of the SNFs' Part B business.

80. Since March 23, 2010, defendants have knowingly failed and refused to report and return overpayments in violation of 42 USC §1320a-7k(d). This requirement was established in 2010 and specifically make the failure to report and return overpayments enforceable under the False Claims Act [31 USC §3729(b)(3) and applies the same broad definitions of "knowing"

and "knowingly" as the FCA. [§1128J, as added March 23, 2010 by P.L. 111-148, Title VI, Subtitle E, §6402(a), 124 Stat. 753.)

A. Shiel and Fresenius Knowingly Submitted Claims to Medicare and Medicaid for Tests That Were Not Reasonable and Necessary by Falsely Submitting Diagnostic Codes

81. Defendants knew that, as a laboratory and Medicare supplier, Shiel, and then Fresenius it had an obligation to submit claims to Medicare only for tests that were reasonable and necessary for the diagnosis or treatment of individual patients. Documentation of medical necessity is required before Medicare and Medicaid will pay for laboratory claims. With only a few exceptions, the programs will not pay for routine checkups or screening tests, defined as "diagnostic procedures performed in the absence of signs or symptoms."

82. Shiel paid its account representatives modest salaries and supplemented those salaries with commissions the representatives could earn based upon the laboratory's revenue earned on their accounts.

83. Physicians and skilled nursing facilities only infrequently inserted ICD-9 (now ICD-10) codes on their patients' laboratory requisition forms and typically ignored the account representatives' requests that they provide this information. Because of this, Shiel would not get paid and the account representatives would not earn commissions unless Shiel itself inserted the codes.

84. Shiel taught its account representatives to insert codes themselves, with no knowledge of whether the codes were proper. As commissioned sales people, their only concern was whether the codes would get Medicare to pay for the tests. Jack Basch and other

Shiel executives directed their account representatives by telling them, "You've got to put down an ICD-9." Or, "You've just got to do it."

85. Shiel office workers routinely received printed "missing diagnosis" sheets for laboratory test requisitions which were unpaid because ICD-9 codes were missing, or because the codes which had been selected did not result in payment. These requisitions would either be put in the account representatives' inboxes, left at billing office desks, or in some cases, delivered to the account representatives.

86. Shiel representatives who had nursing home accounts also routinely inserted codes to justify reimbursement even when newly admitted patients were receiving "baseline" tests which Medicare does not pay for. The patients also had regularly scheduled routine testswhich, in the absence of signs, symptoms, or diagnoses, are also not reimbursable.

87. In the fall of 2014 Shiel and Fresenius helped introduce software which its nursing home accounts would use to order laboratory tests. The software required the nursing homes to enter a diagnostic code for the order to be processed.

88. However, this did little or nothing to meet Medicare's requirement that orders include ICD-9 codes reflecting the medical condition which made the test necessary and defendants' own chief compliance officer acknowledges that at least half of the tests are ordered or billed with improper diagnostic coding.

89. There are two main reasons for this. First, the software-facilitated coding prompt does not require that the nursing home enter the correct code that demonstrates the medical necessity of the test. It does not even require that the nursing home enter a code which, although inaccurate, would nonetheless trick Medicare into paying for the test. Entering any diagnostic code will cause the test requisition to process.

90. Second, defendants prepared "cheat sheets" listing diagnostic codes which would trigger Medicare payment even if they had nothing to do with the patients' condition. Defendants trained nursing home employees to use the "cheat sheets" to enter diagnostic codes which would trick Medicare into paying for the laboratory tests whether or not there was any genuine evidence that the tests were medically necessary.

91. The falsification of ICD-9 and ICD-10 codes was known by Fresenius Laboratories' Chief Operating Officer and the vice-president of Billing and Contracting.

B. Shiel and Fresenius Knowingly Submitted Claims to Medicare and Medicaid for Tests That Were Not Reasonable and Necessary by Adding Orders for Expensive and Unnecessary Tests

92. In 2014, after Fresenius acquired Shiel, a sales contest was held which offered the most successful sales representative a thirty percent commission on accounts generating over $50,000 in monthly billings. The contest winner, Sal Prifitera, boasted that he had done this by automatically adding orders for expensive services such as Vitamin D assays (CPT Code 82306 and Oxidized LDL tests. (CPT Code 83516.)

93. This was hardly the first time Prifitera had done this. In a December 9, 2004 email, Prifitera was singled out for praise by then vice president of sales Todd Schild for getting a medical practice to include ***routine*** Oxidized LDL tests on the chemistry panels it ordered. Schild pointed out that by doing this Prifitera had **doubled** Shiel's sales to this medical group, to $40,000 per month.

94. The expensive oxidized LDL tests are governed by Medicare's general requirement that routine screening tests are not reimbursable.

95. In New York, reimbursement for Vitamin D assays are governed by Local Coverage Determination L29510 promulgated by NGS, which became effective September 1, 2009. Pursuant to this LCD, routine screening tests for Vitamin D insufficiency are not reimbursable, and the assay is only indicated for patients who have been diagnosed with a few very specific diseases.[3] Testing without one of these specific diagnoses may not properly be billed to Medicare.

C. **Defendants Gave Financial Inducements to Physicians in Exchange for Referrals in Violation of the Stark Law and Anti-Kickback Statute.**

96. Defendants have used a variety of means to provide financial inducements to doctors and nursing homes to encourage and reward referring their patients to Shiel.

(A) Physicians are now required to switch their practices to electronic medical records (EMRs). Shiel pays the monthly licensing fee of approximately $200 per month for cloud-based EMR services. Relator is informed and believes and based thereon alleges that these monthly payments are made on behalf of approximately one hundred or more physicians who are customers of Shiel account representative Sal Prifitera.

(B) Relator is informed and believes and based thereon alleges that Shiel allowed itself to be overcharged by another EMR company, ELLKAY LLC, by a factor of approximately 400%, using some or all of the nearly one million dollars in funds generated by

[3] Vitamin D assays are indicated for patients with any of the following conditions: chronic kidney disease State III or greater; osteoporosis osteomalacia; osteopenia; hypocalcemia; hypercalcemia; hypoparathyroidismk; hyperparathyroidism; or rickets. The assay test is also indicated to monitor the effectiveness of Vitamin D replacement therapy in patients with documented Vitamin D. deficiency.

the overcharge to induce physician referrals. Shiel recently authorized one account representative to spend thousands of dollars for a party hosted by a physician, Amir Rabaddi, who gave business to Shiel.

(C) Shiel also provides financial inducements to physicians by placing phlebotomists and other personnel in doctors' offices without charge, or by paying doctors' own employees to draw blood samples. For example, a Shiel employee who is an assistant to sales representative Brian Gluck actually reports to work at a Boro Park, New York OB GYN practice where she performs office functions which directly support the doctors.

D. Shiel Has Given Illegal Financial Inducements to Nursing Homes in Exchange for Referrals

97. When and administrator at a nursing home which gave its clinical laboratory work to Shiel opened an insurance agency as a side business, the administrator asked for and received Shiel's Workers' Compensation insurance account.

98. Shiel also spends thousands of dollars every year on gifts of expensive consumer electronics for its favored skilled nursing facility accounts.

99. Shiel negotiated contracts with nursing homes that offered them large discounts on the SNFs' Medicare Part A labs in exchange for exclusive agreements that gave Shiel all of the SNFs' Part B business.

100. The following nursing homes received discounts on their Part A lab services in exchange for granting Shiel an exclusive agreement for all the SNF's Part B business: Brooklyn United Methodist Church Home (BUMCH), Bushwick Center for Rehabilitation and Health Care, Concord Nursing Center, Inc. (CNC), Croton Bethel NH, Ditmas Park Rehabilitation, Inc., Dry Harbor Nursing Home, Inc., Fieldston Lodge Nursing Home, Inc.,

Friedwald Center, Inc., Friedwald Center for Rehabilitation and Nursing, Grandell Rehabilitation and Nursing Center, Inc., Haym Solomon Nursing Home, Inc., Holliswood Care Center, Marcus Garvey Nursing Home, Inc., New East Side Nursing Home, LLC, New Rochelle Nursing Home, Northern Manor Nursing Home, Inc., Northern Riverview Nursing Home, Inc., Oak Hollow Nursing Center (OHNC), Ossining Bethel NH, Queens Nassau Nursing Home, Inc., Ramapo Manor Center for Rehabilitation and Nursing, Ruby Weston Manor, Inc., The Silvercrest Center for Nursing & Rehabilitation, Sutton Park Center for Nursing & Rehabilitation, LLC, Verrazano Nursing Home, Inc.,, Woodbury Center for Healthcare (WCHC), and Woodcrest Nursing Home, Inc. Relator's principal knows this as he negotiated and received signed contracts from these SNFs that specified discounts on Part A labs in exchange for an exclusive arrangement for their Part B business.

101. Upon information and belief, the nursing homes listed below also received discounts on their Part A lab services in exchange for granting Shiel an exclusive agreement for all of the SNF's Part B business. Alliance Health Associates, Inc (d/b/a Linden Gardens Rehabilitation and Nursing Center), Apex Rehabilitation, Atrium at Park Ridge d/b/a Plaza Regency Care Center (Park Ridge), Belair Care Center, Inc., Berkshire Nursing and Rehabilitation Center, Beth Abraham Health Services, Bishop Charles Waldo MacLean, Inc. (BCWM), Bishop Henry B. Hucles Nursing Home, Cabrini Center for Nursing & Rehabilitation, Cabrini of Westchester for its St. Cabrini Nursing Home, Center for Nursing & Rehabilitation, Cobble Hill Health Center, Inc., Cobble Hill Health Center, Long Term Health Care Program (LTHHCP), Crest Hall Nursing, East Rockaway Care Center, Fieldston Lodge, Flushing Manor Care Center, Inc., Hudson Point at Riverdale, Inc., Huntington Hills Nursing Home, Komanoff Center for Geriatric & Rehab Medicine, KZ Corp d/b/a Atrium at

Wayne Care Center (Atrium), Lawrence Nursing Care Center, Inc., New Sea Crest Health Care Center, Northern Riverview Nursing Home, Inc., PALJR, LLC d/b/a East Neck Nursing & Rehabilitation Center, Palm Gardens Center (PGC), Pelham Parkway Nursing Care & Rehabilitation Facility, Port Jefferson Healthcare Facility, Rockville, Sans Souchi Rehabilitation and Nursing Center (SSRNC), Shoreview, South Shore Rehabilitation and Nursing Center (SSRN), St. Patrick's Home for the Aged and Infirm, The Riverside, and Wayneview Corp d/b/a Wayneview Care Center. Relator's principal knows this as he negotiated contracts with these SNFs that specified discounts on Part A labs in exchange for an exclusive arrangement for Shiel to handle their Part B business.

102. Offering these discounts to the nursing homes was very profitable for Shiel, as for most nursing homes only 15-20% of the lab tests for Medicare patients were billable under Part A, with the remaining 80-85% of their lab tests falling under Part B of Medicare.

103. Relator's principal had personal knowledge of these illegal inducements at the time the original and the first amended complaint were filed because Relator's principal was responsible for getting the nursing home contracts signed, including the Part A discounts in exchange for exclusivity, including Part B. This dated back to the mid-1990's. When Relator's principal began this work at Shiel he had been told that discounts were in exchange for exclusivity were a standard business practice. As he gained more experience in the industry he heard that other laboratories similarly offered pricing arrangements, confirming his mistaken belief that this was a standard industry practice and that nothing was wrong with it. When Relator's principal filed the original and first amended complaint, he had not focused on the illegality of these contract provisions, because it had been brought up by only one nursing home in nineteen years and the fact that they were another form of kickback. Therefore, these allegations were not originally included in the complaint.

104. When Relator's principal began at Shiel, he was responsible for about 20 nursing home contracts; this number grew to about 100 over the time Relator's principal was employed there. All nursing homes were offered discounts on Part A work in exchange for Shiel being the exclusive lab services provider for that SNF's Part B patients. In the contracts Shiel was listed as the "primary provider of laboratory services". This was understood by both Shiel and the nursing home to mean that Shiel was to be to be the ***only*** provider of lab services for the nursing home. All nursing homes wanted at least a 30% discount; most of them received this and Shiel's contracts with the nursing homes included this discount. After execution of a contract, all lab services for the contracted nursing home were provided exclusively by Shiel.

105. Jack Basch and Moshe Kraus required Relator's principal to bring all contracts to them to approve the final discounts. For some nursing homes, Basch would tell Relator's principal what discounts to offer; for others Basch would modify and approve the contract after Relator's principal relayed to him what discount the nursing home wanted. Further discounts were often given at Jack Basch's or Moshe Krause's discretion when the nursing homes were billed for lab services for their Part A patients.

106. Many of the nursing homes received additional discounts above and beyond the contracted discount. One nursing home, Brooklyn United, got an additional discount over and above the 30%. Another, Friedwald Center, got a 40% discount on its part A work in exchange for exclusivity for Shiel for part B labs. This was accomplished by combining the 30% discount in the contract with an additional 10% taken off when Shiel billed for part A work. Similarly, further discounts above the 30% base discount that was detailed in the contracts were offered to about 40% of Shiel's nursing home clients. These clients were known as "Jack's (Basch) clan". Nursing homes that fell into this category included, *inter alia*,

Bridgeview, Midway, Fulton Commons, Mayfair, Silverlake, Cliffside, National Healthcare nursing homes, Huntington Hills, Atrium and Ross Healthcare nursing homes (all located in the State of New York). These further discounts were given twice a year when the nursing home would receive its part A bill from Shiel.

107. Upon information and belief, about 25% of nursing homes never paid their Part A bills at all. When Shiel billed them for lab services for their Part A patients, despite the fact that they were already receiving a significant discount on their Part A bill, these nursing homes simply would not pay at all. Shiel did not undertake serious collection activities. For these nursing homes the effective billing rate was $0.00 for each lab test.

108. For example, Silverlake nursing home and Verrazano nursing home, both owned by Otto Weingarten, never paid their Part A bills. When Shiel billed these homes for Part A labs, they did not pay their bill at all, and laughed when Shiel called to request payment. Shiel did not push back or insist upon payment from Silverlake or Verrazano, as Weingarten's nursing homes were a significant source of Part B business for Shiel.

109. These Part A discounts were substantial inducements to the nursing homes. On average, nursing homes were billed about $50,000 to $60,000 per year for labs for Part A patients. Therefore, the discounts Shiel offered could generate at least $18,000 per year in savings to the nursing homes. For the homes receiving 100% discounts the savings were far higher.

110. These discounts also gave the nursing homes that were receiving these kickbacks the opportunity to pay prices for lab test that were lower than those permitted by the New York Medicaid. Therefore the kickbacks were not only illegal inducements, but also

contravened NY Medicaid fee schedules, which had "best price" requirements that Medicaid pay no more than the lowest amount paid by any other payor.

111. For example, commonly performed and therefore high volume tests such as the comprehensive metabolic panel (CMP), basic metabolic panel (BMP), and Prothrombin time (Protime) fell below the Medicaid price when offered at discounts between 15% and 35% (depending on year). See attached Exhibits A1-A12.

112. In addition, less frequently performed, but more expensive tests such as those for Vitamin D and Ferritin fell below the Medicaid price when offered at discounts up to 30%. See attached Exhibits A1-A12.

113. Because almost all nursing homes received at least a 30% discount on their Part A labs, this resulted in "best price" violations for almost every SNF for whom Shiel offered this inducement.

114. For nursing homes such as Silverlake and Verrazano, which never paid any Part A bills, there was 100% discount on all lab tests, making any test performed for these homes a violation of NY State lab payment regulations.

115. In addition to the discounts on Part A work, Shiel also offered other inducements to nursing homes to secure exclusive arrangements to do all Part B labs. For example, Shiel did not charge the nursing homes for any labs done for patients covered by an HMO.. For example one Blue Cross HMO paid the nursing home an all-inclusive per diem rate which included all laboratory services. By not charging the nursing homes for these labs, Shiel allowed the nursing homes to keep more of the per diem rate paid by the HMO for their own profit.

116. Furthermore, all nursing homes owned by the ownership of Klein and Rubin including *inter-alia* Hopkins Care Center, Oceanside Care Center, Park Terrace, Grandel Care Center, Beach Terrace and Queens Nassau were not charged Part A travel fees for venipuncture (i.e., the travel costs a phlebotomist would incur when traveling to a nursing home to take a patient's blood. This travel fee is a cost that would have come out of the per diem rate paid to the nursing home by Part A. By not charging a nursing home for the travel fee, Shiel allowed the nursing home to keep more of the per diem rate paid by Medicare Part A for its own profit.

117. Silverlake nursing home in NY, received further inducements. A blood gas machine was placed in a broom closet and was deemed a "lab" by Shiel. Shiel paid a monthly fee to Silverlake for this onsite "lab" and stated that Shiel's medical director, Dr. Romano was also medical director of this "lab". Shiel also paid a monthly fee to Silverlake for a respiratory therapist, Elliot Spira, even though Spira was a Silverlake employee, In addition, Shiel paid a monthly fee to Silverlake's medical director. These bogus arrangements provided additional incentive for Silverlake to give Shiel exclusivity for its Part B work. Shiel was particularly motivated to offer incentives to Silverlake, as over 70% of its lab work was covered under Part B.

118. Cliffside nursing home in NY had a similar arrangement with Shiel, where Shiel provided payments to the nursing home for a bogus lab. Shiel was particularly motivated to offer this incentive to Cliffside, as Cliffside also had a large proportion of Part B business.

E. <u>Defendants Knew That These Financial Inducements Were Illegal</u>

119. Defendants knew that compliance with the Stark Law and Anti-Kickback Statute was a condition of payment by Medicare. Defendants explicitly certified that, as a Medicare

supplier, they would comply with all Medicare laws and regulations, including the Stark Law and Anti-Kickback Statute, on Form CMS-855B and CMS-1500 claims forms.

120. Defendants knowingly compensated physicians and skilled nursing facilities in exchange for referrals, in violation of the Stark Law and Anti-Kickback Statute. Defendants paid kickbacks and dispensed gifts expressly to obtain referrals, to increase the number of tests referred, and to prevent customers from affiliating with competitors.

121. At least one Shiel account representative would purchase gifts for customers, and was told to manufacture receipts that "make sense". With company approval, he would turn in fake invoices for repair work or would turn in receipts for expensive personal items that appear to be business-related and would cover the costs of the gifts he had been directed to purchase, thus concealing the inducement in the event of an audit or investigation.

V. THE UNITED STATES AND THE STATES OF NEW YORK AND NEW JERSEY WERE HARMED BY DEFENDANTS' CONDUCT

122. As a result of Defendants' conduct, the Medicare program paid Defendants tens of millions of dollars for false and/or fraudulent claims for laboratory tests.

123. Medicare was directly affected by Defendants' fraudulent schemes. Estimates of Medicare / Medicaid, or Proxy Estimates of SNF residents.

124. Medicare was particularly susceptible to Defendants' fraudulent schemes because it does not require a patient co-payment on laboratory services. Because Medicare patients were not required to pay out-of-pocket for laboratory services, they had no reason to inquire into the charges to Medicare associated with them.

125. The damages to the United States and the States of New York and New Jersey arising from the Defendants' submission of claims to Medicare and Medicaid referred by these physicians in violation of Stark Law is also in the millions of dollars.

126. The damages to the United States and the States of New York and New Jersey arising from the Defendants' submission of claims to Medicare and Medicaid for laboratory tests that were not reasonable and necessary for the diagnosis or treatment of patients, and for which the need was not assessed or documented for individual patients, including the claims referenced in Section IV, E above, likely exceeds tens of millions of dollars.

COUNT I

(Federal False Claims Act: Presentation of False Claims)

(31 U.S.C. § 3729(a)(1) and (a)(1)(A))

127. Relator repeats and reloads and hereby incorporates by reference paragraphs 1 through 97 inclusive set out above as though fully set forth herein.

128. Defendants knowingly presented, or caused to be presented, false and fraudulent claims for payment or approval to the United States and New York and New Jersey Medicaid, including those claims for reimbursement of laboratory drug tests that violated the Stark Law and the Anti-Kickback Statute and that were ordered by physicians for uses that were not reasonable and necessary for the diagnosis or treatment of individual patients.

129. Said claims were presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

COUNT II

(Federal False Claims Act: False Statements Material to False Claims) (31 U.S.C. § 3729(a)(1)(B))

130. Relator repeats and reloads and hereby incorporates by reference paragraphs1 through 97 inclusive set out above as though fully set forth herein.

131. Defendants knowingly made, used, and caused to be made or used, false records or statements — i.e., false statements regarding compliance and coverage for its services and false statements on forms CMS-855B, 837P and CMS-1500—to get false or fraudulent claims paid and approved by the United States.

132. Defendant's false certifications and representations were made to get claims paid even though there was no evidence of medical reasonableness or medical necessity, and payment of the false or fraudulent claims was a reasonable and foreseeable consequence of the Defendant's statements and actions.

133. The false certifications and representations made and caused to be made by Defendant were material to the United States' and New York and New Jersey Medicaid's payment of the false claims.

134. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

COUNT III

FAILURE TO RETURN OVERPAYMENTS FALSE CLAIM

(Federal False Claims Act; 31 U.S.C. § 3729(b)(e)

135. Relator repeats and reloads and hereby incorporates by reference paragraphs1 through 97 inclusive set out above as though fully set forth herein.

136. Defendants, and each of them have known that they had received overpayments under Medicare. Fresenius has known this for two reasons: First, Fresenius' more rigorous compliance program resulted in a nearly twenty percent drop in sales during the first full year after Shiel's acquisition, which certainly should have alerted Fresenius to the likelihood that Shiel had been engaging in fraudulent practices. Second, two of Shiel's leading malefactors, Jack Basch and Moshe Klaus, have continued in senior leadership positions for Fresenius.

137. Defendants have nonetheless refused to conduct audits that are within their power to conduct in the full knowledge that those audits would reveal the precise amount of overpayment refunds due Medicare because each of the previously enumerated false billing schemes.

138. Defendants' refusal to calculate or estimate the amount of overpayment refunds owed is a separate violation of 31 U.S.C. §3729(b)(3) of the False Claims Act.

COUNT IV

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

(NEW YORK STATE FINANCE LAW, - ARTICLE XIII §§ 187 *et seq.*)

139. Relator repeats and reloads and hereby incorporates by reference paragraphs1 through 97 inclusive set out above as though fully set forth herein.

140. The New York Medicaid Provider Enrollment Application requires a certification that the provider agrees to "abide by all applicable Federal and State laws as well as the rules and regulations of other New York State agencies peculiar to the type of program covered by this enrollment application."

141. The New York False Claims Act (NY State Finance Law, Ch. 56 of the Consolidated Laws - Article XIII §§187 *et seq.*) provides in pertinent part as follows:

> §189. Liability for certain acts.
>
> 1. Subject to the provisions of subdivision two of this section, any person who:
>
> (a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> ***
>
> (g) knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or local government;
>
> shall be liable to the states or a local government as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person.

142. Pursuant to Section 188(3) of the New York False Claims Act, proof of specific intent to defraud is not required.

143. As set forth herein, Defendant has violated the New York False Claims Act in New York State Finance Law Ch.56, Article XIII §§ 189(1)(a), 189(1)(b), 189(1)©, and 189(1)(g).

144. As explained in detail Defendants have submitted false claims and/or false records for laboratory tests for which there was no evidence of medical necessity or medical reasonableness, or which were procure through the use of illegal financial inducements; or both.

145. As also explained in detail, Defendants have refused to calculate or repay overpayments despite knowledge that they have received substantial overpayments.

146. The Defendants knowingly violated N.Y. State Fin. Law § 189 and knowingly presented or caused to be made, used and presented hundreds of thousands of false claims to the State of New York from 2008 to the present, by violating the Federal Anti-Kickback Act, as described herein.

147. The State of New York, by and through the State of New York Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

148. Given the structure of the health care systems, the false claims, statements, representations, material omissions, and/or records made by the Defendants had the potential to influence the State of New York's payment decision.

149. As a result of the Defendants' violations of N.Y. State Fin. Law § 189, the State of New York has been damaged.

150. For each violation of the New York False Claims Act, New York is entitled to recover treble damages from Defendant. *See* New York False Claims Act§189 (h).

151. In addition, for each violation of the New York False Claims Act, New York is entitled to recover from Defendant a civil penalty of not less than $6000, and not more than $12,000. *Id.*

152. There are no bars to recovery under N.Y. State Fin. Law. § 190(9), and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.Y. State Fin. Law § 190(2) on behalf of himself and the State of New York.

To the extent that any allegations or transactions herein have been publicly disclosed, Relator has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions. Contemporaneously with filing, Relator has provided all material documents related to this Complaint to the Attorney General of the State of New York. This Complaint details Relator's discovery and investigation of Defendants' fraudulent schemes and is supported by documentary evidence.

COUNT V

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

153. Relator repeats and reloads and hereby incorporates by reference paragraphs1 through 107 inclusive set out above as though fully set forth herein.

154. The New Jersey Medicaid Provider Enrollment Application requires a certification that the provider agrees "to comply with all applicable State and Federal Medicaid laws and policies, and rules and regulations promulgated pursuant thereto " and agrees "to comply with Section 1909 of P.L. 92-603, Section 242© which makes it a crime for persons found guilty of making any false statement or representation of a material fact in order to receive any benefit or payment under the Medicaid Assistance program...." Provider Agreement Between New Jersey Department of Health and Senior Service and Provider, at 1, Items 1 and 5.

> § 2A:32C-3 of the New Jersey Statutes provides liability for any person who-
>
> (a) knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

> (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.
> . . .
>
> (g) Knowingly makes, uses, or causes to be made or used or to be used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

155. Pursuant to §2A:32C-2 proof of specific intent to defraud is not required.

156. As explained in detail Defendants have submitted false claims and/or false records for laboratory tests for which there was no evidence of medical necessity or medical reasonableness, or which were procure through the use of illegal financial inducements; or both.

157. As also explained in detail, Defendants have refused to calculate or repay overpayments despite knowledge that they have received substantial overpayments.

158. The Defendants knowingly violated N.J. Stat. Ann. § 2A:32C-3 and knowingly presented false claims to the State of New Jersey from 2009 to the present, by violating the Federal Anti-Kickback Act, as described herein.

159. The State of New Jersey, by and through the State of New Jersey Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

160. Given the structure of the health care systems, the false claims, statements, representations, material omissions, and/or records made by the Defendants had the potential to influence the State of New Jersey's payment decision.

161. As a result of the Defendants' violations of N.J. Stat. Ann. § 2A:32C-3189, the State of New Jersey has been damaged.

162. For each violation of the New Jersey False Claims Act, New Jersey is entitled to recover treble damages from Defendant under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32-C1–2A:32-C18.

163. In addition, for each violation of the New Jersey False Claims Act, New Jersey is entitled to recover from Defendant a civil penalty of not less than $5,500, and not more than $11,000. *Id.*

164. There are no bars to recovery under N.J. Stat. Ann. § 2A:32C-9(c), and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J. Stat. Ann. § 2A:32C-5(b) on behalf of himself and the State of New Jersey. To the extent that any allegations or transactions herein have been publicly disclosed, Relator has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions. Contemporaneously with filing, Relator has provided all material documents related to this Complaint to the Attorney General of the State of New Jersey.

COUNT VI

(For John Doe Only)

ILLEGAL RETALIATION IN VIOLATION OF

THE FEDERAL FALSE CLAIMS ACT

165. Doe repeats and repleads each and every one of the allegations in Paragraphs 1 through 135, inclusive, as though fully set forth herein.

166. Defendant Shiel moved its primary place of business to New Jersey. Since its sale to Fresenius, the laboratory business has been operated by Spectra Laboratories, in Rockleigh, New Jersey.

167. John Doe is one of the principals who formed the corporate entity which is the Relator in this action. At all times material hereto Doe was employed first by Shiel and then by Spectra which is owned and controlled by Fresenius. Doe brings this claim anonymously because he has already been retaliated against and has been held up in a false light by Fresenius, and fears Fresenius' further retaliation will deprive him of the ability to support his family.

168. Defendants knew that there was a distinct possibility that Doe might become a whistle blower.

169. Doe made his dissatisfaction with Defendants' illegal conduct well known throughout the company. He made numerous complaints to the compliance officer, repeatedly voicing his concern that fabricating and submitting diagnostic codes was illegal and tantamount to Medicare fraud.

170. Doe also warned many of his sales colleagues that submitting codes was illegal and would get them and the company into trouble.

171. Doe also inadvertently used a company email account to forward an email to one of his lawyers, whose email address is mkleiman@quitam.org.

172. Since Fresenius has been a defendant in numerous *qui tam* cases and has paid hundreds of millions of dollars to the United States to settle allegations that it has committed Medicare fraud and Medicaid fraud, it is well aware that "qui tam" refers to a type of law suit brought by a whistle blower in the name of the United States.

173. Finally, as the Court is aware, in January 2017, Fresenius was made aware of the fact that a False Claims Act complaint had been filed against it.

174. On February 21, 2017, within a month of Fresenius receiving this information, Doe was fired while taking two of his children on a college tour.

175. In doing the things hereinabove alleged, Defendants Shiel Medical Laboratory; Shiel Holdings, LLC; Fresenius Medical Care; and Does 1-3, inclusive violated 31 U.S.C.§3730(h).

176. As a direct legal consequence of his wrongful firing, Doe has lost, and shall continue to lose income, commissions, bonuses, and other valuable benefits in an amount uncertain as of this moment, but to be plead and proven at trial.

177. As a consequence of his wrongful firing, Doe has suffered and shall continue to suffer anxiety and emotional distress in an amount uncertain as of this moment, but to be plead and proven at trial.

178. As a consequence of his wrongful firing, Doe has incurred and shall continue to incur legal fees and costs in an amount uncertain as of this moment, but to be plead and proven at trial.

COUNT VII

(For John Doe Only)

ILLEGAL RETALIATION IN VIOLATION OF

THE NEW JERSEY CONSCIENTIOUS EMPLOYEE PROTECTION ACT

179. Doe repeats and repleads each and every one of the allegations in Paragraphs 1 through 149, inclusive set out above, as though fully set forth herein.

180. In raising these complaints and issuing these warnings, Doe had an objectively reasonable and good faith belief that the conduct he was decrying violated the federal False Claims Act and various state statutes, as enumerated *supra*.

181. In doing the things hereinabove alleged, Defendants Shiel Medical Laboratory; Shiel Holdings, LLC; Fresenius Medical Care; and Does 1-3, inclusive violated N.J.S.A. 34:19- 1, *et. seq.* 31 U.S.C. §3730(h), directly and legally causing damage to Doe as hereinabove alleged.

PRAYER FOR RELIEF

Counts I through V

WHEREFORE, the Relator demands and prays that judgment be entered in favor of the United States and the States of New York and New Jersey in against Defendants as follows:

1. For the amount of the damages to the United States or the State of New York or the State of New Jersey, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper;

2. For the Relator, the maximum amount of the Relator's share allowed by law;

3. Reimbursement for all reasonable expenses that Relator incurred in connection with this action;

4. An award of reasonable attorneys' fees and costs; and

5. Such further relief as this Court deems just and proper.

Count VI

WHEREFORE, one of the Relator's Principals, John Doe, demands and prays that judgment be entered in his favor against Defendants Shiel Medical Laboratory; Shiel Holdings, LLC; Fresenius Medical Care; and Does 1-3, inclusive as follows:

6. For two times Doe's lost earnings and benefits;

7. For all future lost earnings and benefits;

8. For an amount sufficient to compensate Doe for his pain, suffering, and emotional distress;

9. Reimbursement for all reasonable expenses, including, *inter alia*, attorney's fees, that Doe incurred in connection with this action; and

10. Such further relief as this Comi deems just and proper.

Count VII

WHEREFORE, one of the Relator's Principals, John Doe, demands and prays that judgment be entered in his favor against Defendants Shiel Medical Laboratory; Shiel Holdings, LLC; Fresenius Medical Care; and Does 1-3, inclusive as follows:

11. For Doe's lost earnings and benefits;

12. For all future lost earnings and benefits;

13. For an amount sufficient to compensate Doe for his pain, suffering, and emotional distress;

14. For punitive or exemplary damages in an amount sufficient to punish the Defendants and to deter future similar misconduct;

15. Reimbursement for a11 reasonable expenses, including, *inter alia*, attorney's fees, that Doe incurred in connection with this action; and

16. Such further relief as this Court deems just and proper.

Respectfully submitted,

Dated: 2/7, 2022

Steven J. Marcus
NY Bar No. 1231307
431 W. 22nd Street
New York, NY 10011
212-989-6187
Sjmarcus3@aol.com

Dated: 2/7, 2022

KLEIMAN / RAJARAM

Mark Allen Kleiman (CSB #115919)
(pro hac vice)
Pooja Rajararm (CSB #241777)
(pro hac vice)
2525 Main Street
Suite 204
310-392-5455
310-306-8491 (fax)
mkleiman@quitam.org
prajaram@quitam.org

Dated: 2/7, 2022

HALLORAN SAGE, LLP

Howard L. Pierce
NY Bar No. HP5655
One Goodwin Square
225 Asylum Street
Hartford, CT 06103
Telephone: 860-297-4655
Fax:(860) 548-000
pierceh@halloransage.com

DEMAND FOR JURY TRIAL

The Relator demands a jury trial in this case.

Respectfully submitted,

Dated: 2/7, 2022

Steven J. Marcus
NY Bar No. 1231307
431 W. 22nd Street
New York, NY 10011
212-989-6187
Sjmarcus3@aol.com

Dated: 2/7, 2022

KLEIMAN / RAJARAM

Mark Allen Kleiman (CSB #115919)
(pro hac vice)
Pooja Rajararm (CSB #241777)
(pro hac vice)
2525 Main Street, Suite 204
Santa Monica, CA 90405
310-392-5455
310-306-8491 (fax)
mkleiman@quitam.org
prajaram@quitam.org

Dated: 2/7, 2022

HALLORAN SAGE, LLP

Howard L. Pierce
NY Bar No. HP5655
One Goodwin Square
225 Asylum Street
Hartford, CT 06103
Telephone: 860-297-4655
Fax:(860) 548-000
pierceh@halloransage.com

CERTIFICATION OF SERVICE

The undersigned certifies that on 2/8/22 a copy of the foregoing **SECOND AMENDED COMPLAINT FOR VIOLATIONS OF FEDERAL FALSE CLAIMS ACT** was placed in the United States Mail, Certified Mail/Return Receipt Requested, first class, postage prepaid, addressed to:

Michael D. Kass
Trial Attorney
U.S. Department of Justice, Civil Division
Commercial Litigation Branch, Fraud Section
U.S. Department of Justice
175 N. Street, NE
Washington, DC 20002
Michael.D.Kass@usdoj.gov

Rachel G. Balaban
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of New York
271 Cadman Plaza East
Brooklyn, New York 11201
718-254-6028 (office)
718-254-6081 (fax)
rachel.balaban@usdoj.gov

Diana Elkind | Senior Counsel
Medicaid Fraud Control Unit
New York State Office of the Attorney General
28 Liberty Street
New York, NY 10005
T: 212-417-4171
Diana.Elkind@ag.ny.gov

Mark Allen Kleiman